

Appl. No. 09/932,538  
Amdt. dated January 24, 2005  
Reply to Office Action of August 24, 2004  
Page 7 of 12

**Amendments to the Drawings**

Please re-include Figure 8 as the last page of the drawings, a copy of which is attached.

Attachment:            Replacement Sheet

## **REMARKS/ARGUMENTS**

### **I. Introduction**

Upon entry of the present amendment, claims 5-7 remain under examination in this application. Figure 8 and its accompanying description have been re-included in the application. No new matter has been added. Also with the response, Applicant submits a declaration from Dr. Relyveld showing a distinction between the material, structural, and functional characteristics of the claimed composition and the composition of the cited prior art – U.S. Patent No. 4,016,252 to Relyveld.

Because the present amendments (1) do not raise new issues requiring further consideration or search, (2) do not introduce new matter, (3) materially reduce the issues for appeal, and (4) place this application into better condition for allowance, entry is appropriate under 37 C.F.R. § 1.116, and is respectfully requested. Applicant respectfully requests reconsideration and allowance of the pending claims.

### **II. Amendments to the Specification and the Drawings**

The Examiner originally objected to Figure 8, stating that “the specification fails to describe Figure 8.” *See* Office action dated April 7, 2004. Without acquiescing to Examiner’s reasoning, Applicant cancelled Figure 8. *See* Response filed June 8, 2004. (One reason for this cancellation was because the ocular embodiment of this invention is being claimed in a related pending application.)

However, now the Examiner's position is that deletion of Figure 8 constitutes new matter because the figure provided support for enablement of the claims. This is a confusing rejection (and one in which the Applicant does not agree), but nonetheless, Figure 8 has been re-included in the application. Applicant is also re-including the description of Figure 8. Applicant submits that the amendments to the specification and Figure 8 remove the grounds for Examiner's rejection, and respectfully request that it be withdrawn.

### **III. 35 U.S.C. §112 Rejections**

The Examiner has rejected claims 5-7 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner's position is that claim 5 is rendered vague and indefinite by the use of the phrase: "induce immunity in a patient."

Applicant continues to submit that the phrase, by its plain and ordinary meaning, means to induce an immunological response in a patient. Applicant refers the Examiner to the following portions of the specification, which discuss possible immunological responses that are sought to be induced:

- cell mediated immunity and antibody responses (page 4, lines 18-24);
- strong Th1 T-cell associated enhancement of microbial immunity, especially IgA production and anti-viral cell-mediated immunity (CMI) (page 5, lines 15-19);
- mucosal IgA immunity (page 5, lines 20-25);
- humoral and cell-mediated immunity, with the mucosal immunity manifested as a humoral response (page 8, line 25 – 26);
- stimulation of B cells which differentiate into antibody-producing plasma cells; antibodies are capable of recognizing extracellular pathogens, while the cell-mediated

component involves T lymphocytes capable of recognizing intracellular pathogens (page 8, line 24 – page 9, line 12);

- systemic and mucosal immunity, with relative absence of side effects and lack of IgE antibody production (page 13, lines 5-10);
- increased survival rates and less severe clinical infection compared to controls, following live-viral challenge (page 13, lines 14-19);
- antigen-specific immunity (page 14, lines 22-25);
- induce higher IgG titers and IgA levels (page 35, lines 16-21).

Based on all of this disclosure in the specification, coupled with the understanding that one of ordinary skill in the art would have, Applicant respectfully submits that the phrase “induce immunity in a patient” is not indefinite or vague. One of ordinary skill in the art would understand the immunity that is sought to be induced by the present invention, particularly when the claim is read in light of the specification. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

#### **IV. 35 U.S.C. §102 Rejection**

The Examiner has also maintained the rejection of claims 5-7 under 35 U.S.C. §102(b) as being anticipated by Relyveld (U.S. Patent 4,016,252). Applicant traverses this rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant submits with this response a declaration by Dr. Relyveld dated November 18, 2004, in which Dr. Relyveld states that “...I have compared the calcium phosphate particles disclosed in the Application to those disclosed in U.S. Patent 4,016,252 (“the ‘252 patent”), issued to me.” See attached declaration of Dr. Relyveld, ¶4. “The calcium

phosphate particles disclosed in the Application are different from the calcium phosphate particles disclosed in the '252 Patent." ¶6. "Unlike the present invention, the '252 Patent does not disclose calcium phosphate particles that are 'substantially smooth' or 'substantially spherical.' Despite efforts, I was unable to obtain the 'substantially smooth' or 'substantially spherical' calcium phosphate particles of the present invention. The inventors of the Application were able to obtain these unexpected results through their novel manufacturing technique." ¶7. "The novel morphology of the calcium phosphate particles of the present invention result in greater control over the degree of antigenic material saturation which can be achieved in the particle. This control leads to greater efficiency in particle production and efficacy in treatment using the particles." ¶8. "The Action is incorrect in stating that the particles in the '252 Patent are 'of the same composition and the same size' as the calcium phosphate particles of the present invention." ¶9.

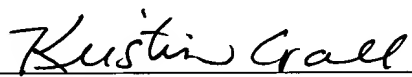
Because Applicant has met its burden of "show[ing] a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art," Applicant respectfully requests withdrawal of this rejection and prompt issuance of a patent containing the pending claims.

Attachment: Relyveld Declaration

### CONCLUSION

Applicant respectfully submits that claims 5-7 are in condition for immediate allowance, and requests early notification to that effect. If any issues remain to be resolved, the Examiner is respectfully requested to contact the undersigned at 404.815.6147 to arrange for a telephone interview.

Respectfully submitted,

  
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